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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,130	01/20/2004	Michael Smith	117622-00105	6639

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EXAMINER	
TOTH, KAREN E	
ART UNIT	**PAPER NUMBER**
3735	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/759,130	SMITH ET AL.	
	Examiner	Art Unit	
	Karen E. Toth	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *28 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 8-18, 23-32* is/are rejected.

7)☒ Claim(s) *4-7,19-22,33 and 34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The second step of claim 33 calls for measuring blood pressure, which in the remainder of the application is abbreviated as "BP". Step (c) of claim 33 calls for calculating pulsatile flow using pulse volume and blood pressure as PF = PV x HR – HR is not present at any other point in the claim. In claim 4, which is similar to claim 33, HR is used to represent heart rate, which is not measured in claim 33.

4. Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The second component of claim 34 calls for measurement of blood pressure, which in the remainder of the application is abbreviated as "BP". The third component of the system of claim 34 calls for calculating pulsatile flow using pulse volume and blood pressure as PF = PV x HR – HR is not present at any other point in

the claim. In claim 19, which is similar to claim 34, HR is used to represent heart rate, which is not measured in claim 34.

Claim Rejections - 35 USC § 102

5. Claims 1, 9-13, 16, and 24-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Raines (US Patent 6149587).

Regarding Claim 1, Raines discloses a method of measuring peripheral vascular function comprising measuring the peripheral pulse volume per length of a subject (column 6, lines 31-36); measuring the blood pressure of the subject (column 6, lines 60-62); and calculating a quantity that is a mathematical function of the patient's vascular function based upon the measured pulse volume and blood pressure (see "Ankle/Arm Index" in Figure 16 – Ankle/Arm Index is an alternate term for Ankle/Brachial Pulse Index, which is the ratio between the systolic arm blood pressure and the systolic ankle blood pressure and is therefore a mathematical function).

Regarding Claim 9, Raines further discloses using a display monitor to display the results of testing, measurements, and analysis (column 3, lines 11-14).

Regarding Claim 10, Raines further discloses using a storage device to store patient data for later review (column 17, lines 39-41).

Regarding Claim 11, Raines further discloses using a communication link (element 14) to transmit data to a remote device (element 12; Figure 1).

Regarding Claim 12, Raines further discloses performing the method using a device that integrates all the components (element 10; Figure 1).

Regarding Claim 13, Raines further discloses that pulse volume measurements are taken using a pulse volume recorder (column 11, lines 6-7); that blood pressure measurements are taken using a plethysmograph; that computing steps are performed using examination and analyzing units; and that said devices are linked only electronically (column 2, line 66 to column 3, line 1).

Regarding Claim 14, Raines further discloses that the data signals generated by physiological measurements are automatically sent to the computing unit (column 3, lines 4-6).

Regarding Claim 15, Raines further discloses that vascular testing data such as blood pressure and other tests may be manually input to the computer system (column 16, lines 58-64).

Regarding Claim 16, Raines discloses a system for measuring peripheral vascular function comprising a pulse volume per length measurement device (column 6, lines 31-36); a blood pressure measurement device (column 6, lines 60-62); and a computing unit (elements 12 and 16) that is used to calculate quantity that is a mathematical function of the patient's vascular function based upon the measured pulse volume and blood pressure (column 21, lines 58-59; see "Ankle/Arm Index" in Figure 16 and explanation attached to rejection of claim 1).

Regarding Claim 24, Raines further discloses that the system comprises a display device (element 17) that is used to display the results of testing, measurements, and analysis (column 3, lines 11-14).

Regarding Claim 25, Raines further discloses that the computing component of the system comprises a storage device that is used to store patient data for later review (column 17, lines 39-41).

Regarding Claim 26, Raines further discloses that the system comprises a communication link (element 14) that is used to transmit the patient data to a remote location for review (element 12; Figure 1).

Regarding Claim 27, Raines further discloses that the system components are contained within an integrated device (column 2, line 66 to column 3, line 1).

Regarding Claim 28, Raines further discloses that the system components are provided separately (column 2, line 66 to column 3, line 1).

Regarding Claim 29, Raines further discloses that the system components electronically communicate and automatically transfer data (column 3, lines 4-7).

Regarding Claim 30, Raines further discloses that the a manual input device (element 140) maybe used to enter data such as blood pressure and other vascular testing results (column 16, lines 58-64).

Regarding claims 31 and 32, the Ankle/Arm Index, or Ankle/Brachial Index, of Raines is well-known in the art as a function that measures limb vascular compliance and resistance, since the ratio between the ankle and arm blood pressures provides an indication of occlusions (which create resistance) and calcification of vessels (which affects compliance) in the peripheral limbs.

Claim Rejections - 35 USC § 103

6. Claims 2, 3, 8, 17, 18, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raines in view of Chio (US Patent 6165130).

Regarding Claim 2, Raines discloses all the elements of the current invention, as applied to Claim 1 above, except for the method comprising measuring the patient's systolic and diastolic blood pressures, and using the measurements to calculate the patient's pulse pressure. Raines further discloses measuring the patient's systolic blood pressure (column 6, lines 60-62), but does not disclose measuring diastolic blood pressure.

Chio teaches a method of cardiac monitoring comprising measuring both the systolic and diastolic blood pressures of a patient (column 18, lines 19-21 and 33-36), and using the blood pressure measurements to calculate the patient's pulse pressure (column 6, lines 57-58), in order to provide a more complete analysis of the patient's cardiac condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed the method of Raines and further measured systolic and diastolic blood pressure for use in calculating pulse pressure, as taught by Chio, in order to provide a more complete analysis of the patient's cardiac condition.

Regarding Claim 3, Raines further discloses measuring the patient's pulse as part of the cardiac evaluation method (column 33, lines 57-60; Figure 36).

Regarding Claim 8, Raines in view of Chio discloses all the elements of the current invention, as applied to claim 2 above, except for the step of calculating vascular compliance as pulse volume divided by pulse pressure.

Chio further discloses calculating the compliance of a vessel as the change in vessel volume divided by the change in vessel pressure (equation 2; column 8, line 66; column 9, lines 4 and 11-12) in order to evaluate a subject's hypertension.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed the measurements of Raines in view of Chio, with the additional step of calculating the compliance of a vessel, as taught by Chio, in order to evaluate a subject's hypertension.

Regarding Claim 17, Raines discloses all the elements of the current invention, as applied to Claim 16 above, except for the blood pressure measuring device measuring the systolic and diastolic blood pressures of the patient and using the blood pressure measurements to calculate the patient's pulse pressure. Raines further discloses using the blood pressure measuring device to measure the patient's systolic blood pressure (column 6, lines 60-62), but does not disclose measuring diastolic blood pressure.

Chio teaches a system for cardiac monitoring comprising using a blood pressure measuring device to measure both the systolic and diastolic blood pressures of a patient (column 18, lines 19-21 and 33-36), and using the blood pressure measurements to calculate the patient's pulse pressure (column 6, lines 57-58), in order to provide a more complete analysis of the patient's cardiac condition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the system of Raines with the additional ability to capture systolic and diastolic blood pressure measurements and use the measurements

to calculate the patient's pulse pressure, as taught by Chio, in order to provide a more complete analysis of the patient's cardiac condition.

Regarding Claim 18, Raines further teaches using the patient's pulse as part of one of the system components of the patient's cardiac evaluation (column 33, lines 57-60; Figure 36).

Regarding Claim 23, Raines in view of Chio discloses all the elements of the current invention, as applied to claim 17 above, except for the system calculating the compliance of a vessel as pulse volume divided by pulse pressure.

Chio further teaches that the system calculates the compliance of a vessel as the change in vessel volume divided by the change in vessel pressure (equation 2; column 8, line 66; column 9, lines 4 and 11-12) in order to evaluate a subject's hypertension.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the system of Raines in view of Chio, with the additional ability to calculate the compliance of a vessel, as taught by Chio, in order to evaluate a subject's hypertension.

Allowable Subject Matter

7. Claims 4-7 and 19-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the method and structure of claims 4-7 and 19-22, including, *inter-alia*, calculating a pulsatile flow as the product of peripheral pulse volume per length times heart rate.

Response to Arguments

8. Applicant's arguments filed 28 November 2006 have been fully considered but they are not persuasive. Applicant asserts that calculation of an ankle/arm index is not a mathematical function of peripheral vascular function. The Examiner disagrees – since the ankle/arm index, or ankle/brachial index, is the ratio of systolic arm blood pressure to systolic ankle blood pressure, it is clearly a mathematical function. Further, since the function is the comparison of blood pressures from peripheral limbs, it is also representative of peripheral vascular function.

The rejections stand as FINAL.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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